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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,902	11/03/2006	Egil Jellum	Q90288	7146

23373 7590 05/12/2011

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
05/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/549,902	JELLUM ET AL.	
	Examiner	Art Unit	
	FRANK CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment to the disclosure is objected to because of the following informalities:

Pursuant to 37 CFR 1.121 amendment to the Specification can be by way of amendment to a paragraph, amendment to a section or substitute specification. The Applicant's amendment to Example 18 of the Specification filed on 3/16/2011 does not fall within any of the three permissible methods of amending the Specification. For amending paragraphs, the amendment should just have an instruction identifying where the paragraph is located and just the paragraph which is being amended with markings.

Appropriate correction is required.

Claim 1 is objected to because of the following informalities: Claim 1 ends in a quotation mark. Please delete the quotation mark.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,851,556 in view of US 5,866,168, Hahn et al. (US Pat. 5,804, 203), Denhem et al., Remington's, Decaris et al., Lambert et al. and WO 02/09763, each in view of either Mak (US 6,190,691)or Scholz et al. (US 6,951,642),

The claimed invention is directed to method of treating inflammation where the inflammation is sub-dermal and in soft tissue by topically administering strontium.

US 5,851,556 disclose that strontium is substance P antagonist, that strontium can be used to treat skin acne, neurodermatitis, asthma, allergic bronchitis, allergic rhinitis, rheumatic and post-tramatic pain, gastrointestinal conditions and that the composition can be applied topically and include adjuvants which are customary in the pharmaceutical and/or dermatological field, such as solvents and hydrophilic active agents, such as polyols (Column 6, lines 20-68, Column 7, lines 1-6, Column 9, lines 26-38, Column 11, lines 14-16, Column 12, lines 45-68, Column 13, lines 1-21).

US 5,866,168 disclose that strontium is a substance P antagonist and that substance P antagonists are effective in the treatment of pain, inflammatory diseases, such as rheumatoid arthritis, psoriasis, acne, colitis, Crohn's disease, gastritis, gastroenteritis, rheumatic diseases, conjunctivitis, uveitis, ocular pruritus, blepharitis, etc. (Column 1).

Hahn et al. disclose that skin conditions such as psoriasis produce an intrinsic skin irritation (Column 3, lines 35-50). It is disclosed that strontium is effective in suppressing skin irritation due to sources such as chemical and environmental exposure or tissue inflammation, injury or skin pathology (Column 9, lines 13-25). It is disclosed that the amount strontium can be reduced if a skin penetration-enhancing is added (Column 14, lines 54-68). It is disclosed that the strontium cation is combined with a suitable anion, such as nitrate, chloride, bromide, iodide, acetate, amino acids, EDTA, etc. (Column 16, lines 10-38). It is disclosed that the other active ingredients can be added such as anti-acne drugs (Column 19, lines 53-55).

Denhem et al. disclose that radiation therapy cause inflammation of skin tissues (page 132).

Remington's discloses that dimethyl sulfoxide is a permeation enhancer but is also effective as an anti-inflammatory agent (Page 1121).

Decaris et al. disclose that substance P is a well known mediator of neurogenic inflammation and plays a role in the development of rheumatoid arthritis and that local inflammation can produce degenerative articular effects from a distance, through systemic or cellular transmission pathways (pages 1951, 1952, 1957, 1958).

Lambert et al. disclose that rheumatoid arthritis is an autoimmune disease characterized by inflammation of the synovial membrane of multiple joints and that substance P has pro-inflammatory properties (Page 269).

WO 02/09763 disclose transdermal delivery of anti-inflammatory drugs with tetraglycol and water (Page 6).

Mak or Scholz et al. disclose that tetraglycol is a permeation enhancer (Mak at Column 51, lines 1-27, Scholz et al. at Column 14, lines 2-4).

US 5,851,556 disclose that strontium is substance P antagonist, that substance P is involved in the transmission of pain and in diseases of the central nerous system, respiratory and inflammatory diseases, gastrointestinal diseases, rheumatic diseases and some dermatological diseases such as acne, that strontium can be used to treat skin acne, neurodermatitis, asthma, allergic bronchitis, allergic rhinitis, rheumatic and post-tramatic pain, gastrointestinal conditions and that the composition can be applied topically and include adjuvants which are customary in the pharmaceutical and/or dermatological field, such as solvents and hydrophilic active agents, such as polyols. The difference between US '556 and the claimed invention is that US'556 does not expressly disclose treatment of inflammation which is sub-dermal and in soft-tissue, the use of dimethylsulphoxide (DMSO) as a permeation enhancer, the addition of tetraglycol and the

treatment of inflammation associated with radiation therapy or arthritis. However, the prior art amply suggests the same as Hahn et al. discloses that strontium is effective in treating irritation where one of the causes of irritation include tissue inflammation; Remington's discloses that DMSO is an anti-inflammatory and permeation enhancer; Denham et al. disclose that radiation therapy can cause inflammation of the skin; US 5,866,168 disclose that strontium is a substance P antagonist and that substance P antagonists are effective in the treatment of pain, inflammatory diseases, such as rheumatoid arthritis, psoriasis, acne, colitis, Crohn's disease, gastritis, gastroenteritis, rheumatic diseases, conjunctivitis, uveitis, ocular pruritus, blepharitis, etc.; Decaris et al. and Lambert et al. disclose that substance P is pro-inflammatory and mediates the development of rheumatoid arthritis; WO 02/09763 disclose transdermal delivery of anti-inflammatory drugs with tetraglycol and water; and Mak or Scholz et al. disclose that tetraglycol is a permeation enhancer.

As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that strontium would be effective in treating various inflammatory conditions including that caused by radiation therapy and rheumatoid arthritis, that DMSO and tetraglycol would increase the bioavailability of the strontium and that DMSO would provide added anti-inflammatory activity and that strontium would be effective in inhibiting inflammation in sub-dermally and in soft tissues as strontium is a substance P antagonist and substance P antagonists are disclosed to be effective in treatment of inflammation, including rheumatic inflammation, gastrointestinal inflammation and eye tissue inflammation.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 9, 2011

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616